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Atty. Dkt. No. 066683-0198

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Robert MARTUZA et al  
Title: REPLICATION-COMPETENT HERPES SIMPLEX  
VIRUS MEDIATES DESTRUCTION OF  
NEOPLASTIC CELLS  
Appl. No.: 10/788,410  
Filing Date: March 1, 2004  
Examiner: Not yet assigned  
Art Unit: 1644

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.



**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding Japanese application.

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

10/4/04

By

[Signature]

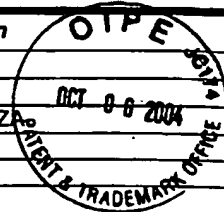
key no. 43445

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

[Signature] Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768

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Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: October 6, 2004  (use as many sheets as necessary)				Application Number	10/748,410
				Filing Date	March 1, 2004
				First Named Inventor	Robert MARTUZA
				Group Art Unit	1644
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	066683-0198



U.S. PATENT DOCUMENTS						
Examine r Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS								
Examine r Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examine r Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
9/2		James M. MARKERT M.D. et al., "Reduction and Elimination of Encephalitis in an Experimental Glioma Therapy Model with Attenuated Herpes Simplex Mutants that Retain Susceptibility to Acyclovir", Neurosurgery, Vol. 32, No. 4, April 1993, pp. 597-603.	
		David J. GOLDSTEIN et al., "Herpes Simplex Virus Type 1-Induced Ribonucleotide Reductase Activity Is Dispensable for Virus Growth and DNA Synthesis: Isolation and Characterization of an ICP6 lacZ Insertion Mutant", Journal of Virology, Vol. 62, No. 1, Jan. 1988, pp. 196-205.	
		Richard J. WHITLEY et al., "Replication Establishment of Latency, and Induced Reactivation of Herpes Simplex Virus γ <sub>1</sub> 34.5 Deletion Mutants in Rodent Models", J. Clin. Invest. Volume 91, June 1993, pp. 2837-2843	
		Cynthia A. BOLOVAN et al., "ICP34.5 Mutants of Herpes Simplex Virus Type 1 Strain 17syn+ Are Attenuated for Neurovirulence in Mice and for Replication in Confluent Primary Mouse Embryo Cell Cultures", Journal of Virology, Jan. 1994, Vol. 68, No. 1, pp. 48-55.	

Examiner Signature	<i>Joe W. Weller</i>	Date Considered	9/25/09
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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Applicant: Robert MARTUZA et al  
Title: REPLICATION-COMPETENT HERPES SIMPLEX  
VIRUS MEDIATES DESTRUCTION OF NEOPLASTIC  
CELLS  
Appl. No.: 10/788,410  
Filing Date: 03/01/2004  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

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**UNDER 37 CFR §1.56**

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Sir:

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**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

23 July 2004

By

Stephen A. Bent

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768


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Substitute for form 1449B/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: July 23, 2004 (use as many sheets as necessary)		Application Number	10/788,410
		Filing Date	03/01/2004
		First Named Inventor	Robert MARTUZA
		Group Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Sheet 1 of 1	Attorney Docket Number	066683-0198	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	A1		WO 92/03563		CENTRAAL DIERGENEESKUNDIG INSTITUUT	3/5/1992	
	A2		WO 96/39841		GEORGETOWN UNIVERSITY	12/19/1996	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	A3	International Search Report		
	A4	Klaus ROEMER et al., "Transduction of foreign regulatory sequences by a replication-defective herpes simplex virus type 1: The rat neuron-specific enolase promoter", Virus Research 35 (1995) pp. 81-89.		
	A5	Shin-ichi MIYATAKE et al., "Transcriptional Targeting of Herpes Simplex Virus for Cell-Specific Replication", Journal of Virology, Vol. 71, No. 7, July 1997, pp. 5124-5132.		
	A6	R.G. VILE et al., "Targeting of cytokine gene expression to malignant melanoma cells using tissue specific promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.		
	A7	C.A. KEECH et al., "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.		
	A8	Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific <i>trans</i> -acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.		
	A9	Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.		
	A10	Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research, 53, pp. 962-967, 1993.		
	A11	Y. MIYAO et al., "Selective expression of foreign genes in glioma cells: use of the mouse myelin basic protein gene promoter to direct toxic gene expression", Journal of Neuroscience Research, vol. 36, 1993, pp. 472-479.		

Examiner Signature		Date Considered	9/25/04
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